

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 03 MAR 2004

WIPO PCT

Applicant's or agent's file reference 21000524	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)
International application No. PCT/EP 02/14655	International filing date (<i>day/month/year</i>) 20.12.2002	Priority date (<i>day/month/year</i>) 28.12.2001	
International Patent Classification (IPC) or both national classification and IPC A61F2/24			
Applicant EDWARDS LIFESCIENCES AG et Al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

I ☒ Basis of the opinion

II ☐ Priority

III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability



IV ☒ Lack of unity of invention

V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

Date of submission of the demand 14.07.2003	Date of completion of this report 27.02.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Mary, C Telephone No. +31 70 340-4409 

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EXAMINATION REPORT**

International application No. **PCT/EP 02/14655**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-48 as originally filed

Claims, Numbers

1-37 as originally filed

Drawings, Sheets

1/25-25/25 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 13-20

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 13-20

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

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☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-12 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-12
	No: Claims	
Inventive step (IS)	Yes: Claims	1-12
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV

Lack of unity of invention

1. The application as presently claimed does not meet the requirements of unity of invention of Rule 13(1)PCT. The application refers to 4 different inventions, namely:

- 1) Claims 1-12: a device for reshaping a cardiac valve comprising a fixing means, a shape-changing member and delaying means.
- 2) Claims 21-30: an apparatus for treating mitral annulus dilatation comprising a proximal stent section, a distal anchor and means for drawing the distal anchor towards the proximal stent section.
- 3) Claims 31-33: an apparatus for treating mitral annulus dilatation comprising a catheter, a balloon and a stent.
- 4) Claims 34-37: an apparatus for treating mitral annulus dilatation comprising proximal and distal ball segments, each comprising a proximal and distal ball with a lumen and a hollow rod extending therebetween, the ball segments being connected by a connecting segments.

The document WO0100111 cited in our search report discloses a device for reshaping a cardiac valve comprising a fixing means, a shape-changing member and delaying means.

Beyond this prior art, the special technical features (in the meaning of Rule 13.2 of the P.C.T) left in the independant claims 1, 21, 31, 34 of the application are:

In independent claim 1: none.

In independent claim 21: an apparatus for treating mitral annulus dilatation comprising a proximal stent section, a distal anchor and means for drawing the distal anchor towards the proximal stent section.

In independent claim 31: an apparatus for treating mitral annulus dilatation comprising a catheter, a balloon and a stent.

In independent claim 34: an apparatus for treating mitral annulus dilatation comprising proximal and distal ball segments, each comprising a proximal and distal ball with a lumen and a hollow rod extending therebetween, the ball segments being connected by a connecting segments.

No same or correspondent special technical feature can be found between the

independent claims 1, 21, 31, 34. There is therefore no technical relationship involving same or corresponding special technical features between the independent claims 1, 21, 31, 34.

The inventions defined in the above-mentioned claims are not linked by a common inventive concept in the sense of Rule 13.1 PCT.

Since the applicant did not reply to the invitation to pay extra fees, the examination is limited to the first invention claimed, namely claims 1-12.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following document:

D1: WO 01 00111 A (KIMBLAD PER OLA ;SOLEM JAN OTTO (SE)) 4 January 2001
(2001-01-04)

3. The document WO 01 00111 is regarded as being the closest prior art to the subject-matter of claim 1 and discloses (the references in parentheses applying to this document) (see D1, page 5, line 19 to page 8, line 25) : a device (8) for reshaping a cardiac valve, said device being elongate and having such dimensions as to be insertable into a cardiac vessel and having two states, in a first state of which the device has a shape that is adaptable to the shape of the vessel and to the second state of which the device is transferable from said first state, said device comprising a fixing means (10) for fixing the ends of the device within the vessel, when the device is first positioned therein, a shape-changing member (9, 22, 26, 27) for transferring the device to the second state by reshaping it and a delay means (11).

4. The subject-matter of claim 1 thus differs from this disclosure in the delay means is resorbable. Therefore the subject-matter of claim 1 is new and meets the requirements of Art.33(2)PCT.

5. The features cited at point 4 serve to delay the change of shape of the device (and thereby the change of shape of the adjacent cardiac valve) to allow a more secure fixation of the device by healing on the vessel wall before the change of shape occurs.

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None of the available prior art documents suggests the combination of said features of claim 1. Therefore claim 1 involves an inventive step and meets the requirements of Art.33(3)PCT.

6.The device disclosed in claim 1 is industrially manufacturable and therefore claim 1 meets the requirements of Art. 33(4)PCT.

7.Claims 2 to 12 refer to further embodiments of the device of claim 1 and in view of that meet the requirements of Art. 33(2), (3), and (4) PCT as well.

Remarks:

8.Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

9.The description discloses 2 technical fields of the invention, 2 backgrounds, 2 summaries, 2 brief descriptions of the drawings and 2 detailed descriptions of preferred embodiments.